

REMARKS

Claims 1-14 have been amended to recite compositions comprising an antigen and an oligonucleotide in view of the fact that claim 19 appears to be free of the prior art based on lack of a prior art rejection. Claim 19 has therefore been canceled as duplicative of amended claim 1. Support for these amendments can be found, for example, at p. 9, ll. 21-28.

Claim 6 has been amended to clarify that when there are more than two TTN_1N_2TT units and, therefore, two or more N_3 nucleotides separating the units, the identity of each N_3 is independent of the identity of every other N_3 . Support for this amendment can be found on p. 8, ll. 1-11, of the specification.

Claim 8 has been amended to remove the definitions of A, T, C, and G as it is believed their recitation is unnecessary; the meaning of the symbols are self-evident to those of ordinary skill in the art and defined in the specification.

Claims 1 and 21 has also been amended to recite 14 of the 16 possible sequences TTN_1N_2TT wherein N_1 and N_2 are independently A, T, C, or G. Omitted from this listing are the sequences in which N_1N_2 is CG or TT. Support for these sequences can be found throughout the specification, including, but not limited to the sequences listed on p. 11 of the specification.

Furthermore, the applicants respectfully submit that because the genus of sequences TTN_1N_2TT wherein N_1 and N_2 are independently A, T, C, or G (as recited throughout the specification) is so small, one of ordinary skill in the art would immediately envisage each member of the genus and appreciate that the applicants had possession of each member. The applicants are now choosing to recite 14 of the 16 species in the claims.

Claim 21 has been amended to recite that the oligonucleotide is administered with or separately from the antigen. Support for this amendment can be found on p. 9, ll. 21-28, of the specification.

New claims 22-35 have been added. Claims 22-28 correspond to the method of claim 20, each incorporating the limitations of claims 2-8, respectively, and claims 29-35 correspond to the method of claim 21, each incorporating the limitations of claims 2-8, respectively, as well.

New claims 36-43 have been added. These claims are directed to methods of stimulating an immune response in a human by administration of the recited oligonucleotide. Support for these

claims can be found throughout the specification, including, for example, p. 6, ll. 16-36, and p. 9, ll. 35-38, which describe uses for the oligonucleotide of the invention and composition comprising the oligonucleotide of the invention, respectively.

The arguments for patentability presented below apply equally to new claims 22-43.

Rejection of claims 1-14 and 19-21 under 35 U.S.C. § 112, first paragraph, and refusal to accord the benefit of applicants' earliest priority claim

The Office rejected claims 1-14 and 19-21 as failing to comply with the written description requirement. The basis for the rejection was that the specification did not provide support for the recitation "in which N₁ and N₂ are not both thymines." The applicants' claim to the benefit of priority to French applications 99/07457 (filed June 8, 1999) and 99/10378 (filed August 6, 1999) was denied for the very same reason, *i.e.*, because the priority application did not support the recitation of "in which N₁ and N₂ are not both thymines." For the following reasons the applicants traverse.

Recitation of "sequences TTN₁N₂TT wherein N₁ and N₂ are independently A, T, C, or G" in the claims and throughout the specification (*e.g.*, p. 2, l. 25-32). This support is also found in the French priority documents (*e.g.*, p. 2, ll. 12-17 of both FR 99/07457 and FR 99/10378). The quoted phrase defines a genus of 16 possible sequences. Because of the explicit definition of the sequence and the very small number of members of the genus, one of ordinary skill in the art would immediately envision each and every member of the genus and understand that the applicants had possession of each and every sequence. By including the phrase "in which N₁ and N₂ are not both thymines" in the claims, the applicants were merely defining which of the 16 disclosed species they wished to claim (*i.e.*, those other than "TTTTTT").

Nevertheless, the claims have now been amended, and the phrase "in which N₁ and N₂ are not both thymines" deleted. The claims now explicitly recite 14 sequences having different combinations of N₁ and N₂. Oligonucleotides with these sequences are found on p. 11 of the specification and on pages 7-8 of FR 99/07457 and 9-10 of FR 99/10378. In addition, as explained above, the recitation of "sequences TTN₁N₂TT wherein N₁ and N₂ are independently A, T, C, or G" also provides written description support because it describes a very small genus

in which each member would be readily envisioned by one of ordinary skill in the art and understood to be within the applicants' possession.

If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient").

MPEP § 2163.

In view of the foregoing, the applicants respectfully request reconsideration and withdrawal of the § 112 rejection and refusal to accord the benefit of priority to the French applications.

Rejection of claims 1-3 and 9-14 under 35 U.S.C. § 102(b)

The Office rejected claims 1-3 as anticipated by Lang. The applicants submit that the present claims are entitled to the benefit of the 1999 filing date of the French priority documents for the reasons explained above, and, therefore, Lang is not prior art against the claims. Reconsideration and withdrawal of this rejection is respectfully requested.

Rejection of claims 1-5 and 9-14 under 35 U.S.C. § 102(b)

The Office rejected claims 1-5 and 9-14 as anticipated by Sanchez-Pescador *et al.* (US 5,618,674), which the Office stated disclosed an amplifier probe oligonucleotide that met the structural limitations of the claims. Claims 1-5 and 9-14 now recite compositions comprising an oligonucleotide and an antigen. Sanchez-Pescador *et al.* does not disclose such a composition. Nor does Sanchez-Pescador *et al.* teach administration of the probe oligonucleotides to humans. Accordingly, Sanchez-Pescador *et al.* does not anticipate the present claims. Reconsideration and withdrawal is respectfully requested.

Rejection of claims 1-4 and 9-14 under 35 U.S.C. § 102(b)

The Office rejected claims 1-4 and 9-14 as anticipated by Mayer *et al.* (US 5,574,142), which the Office stated disclosed an oligonucleotide peptide linker that met the structural limitations of the claims. Claims 1-4 and 9-14 now recite compositions comprising an oligonucleotide and an antigen. Mayer *et al.* does not disclose such a composition.

Furthermore, the oligonucleotides disclosed in Mayer *et al.* are modified for linkage to a peptide. In particular, the sequence cited in the Office Action (SEQ. ID. NO. 9) is a 5'-hexylamine oligonucleotide (see col. 22, ll. 5-20. Mayer *et al.* does not teach or suggest combining the oligonucleotides in a composition with an antigen, nor administering the oligonucleotides to a human, with or without an antigen.

In view of the foregoing, therefore, Mayer *et al.* does not anticipate the present claims.

Reconsideration and withdrawal is respectfully requested.

Rejection of claims 1-3 and 9-14 under 35 U.S.C. § 102(b)

The Office rejected claims 1-3 and 9-14 as anticipated by Herman (WO 97/46705), which the Office stated disclosed a BRAC2 primer oligonucleotide that met the structural limitations of the claims. Claims 1-3 and 9-14 now recite compositions comprising an oligonucleotide and an antigen. Herman does not disclose such a composition. Nor does Herman disclose administration of the primer oligonucleotides to humans. Accordingly, Herman does not anticipate the present claims. Reconsideration and withdrawal is respectfully requested.

Rejection of claims 1-3 and 9-14 under 35 U.S.C. § 102(b)

The Office rejected claims 1-3 and 9-14 as anticipated by Gonzalgo *et al.* (US 6, 251,594), which the Office stated disclosed a PCR primer oligonucleotide that met the structural limitations of the claims. Claims 1-3 and 9-14 now recite compositions comprising an oligonucleotide and an antigen. Gonzalgo *et al.* does not disclose such a composition. Nor does Gonzalgo *et al.* teach administration of the oligonucleotides to humans. Accordingly, Gonzalgo *et al.* does not anticipate the present claims. Reconsideration and withdrawal is respectfully requested.

In view of the foregoing amendments and remarks, the applicant submits that the claims are in condition for allowance, which is respectfully solicited. If the examiner believes a teleconference will advance prosecution, he is encouraged to contact the undersigned as indicated below.

Respectfully submitted,

Date: December 13, 2005



Michael S. Greenfield
Registration No. 37,142

Telephone: 312-913-0001
Facsimile: 312-913-0002

McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, IL 60606